DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
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October 8, 2015

Progentix Orthobiology B.V.
Yvonne P. Bovell
QA/RA Manager
Professor Bronkhorstlaan 10D, Building 48
3723 MB Bilthoven
The Netherlands

Re: K151584
Trade/Device Name: AttraX Putty
Regulation Number: 21 CFR 888.3045
Regulation Name: Resorbable calcium salt bone void filler device
Regulatory Class: Class II
Product Code: MQV
Dated: August 27, 2015
Received: August 31, 2015

Dear Ms. Bovell:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K151584

Device Name
AttraX Putty

Indications for Use *(Describe)*
AttraX Putty is intended for use as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. AttraX Putty is intended to be used in conjunction with autograft bone as a bone graft extender and gently packed into bony voids or gaps in the posterolateral spine. AttraX Putty provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary AttraX Putty

Date: 10 June 2015

ADMINISTRATIVE INFORMATION

Submitter details:

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Contact person:

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DEVICE NAME AND CLASSIFICATION

Trade/Proprietary Name	AttraX Putty
Common Name	Filler, bone void, calcium compound
Classification Name	Resorbable calcium salt bone void filler device
Classification Regulations	21 CFR 888.3045, Class II
Product Code	MQV
Classification Panel	Orthopaedic and Rehabilitation Devices Panel
Reviewing Branch	Restorative Devices Branch

INTENDED USE

AttraX Putty is intended for use as a bone void filler for bony voids or gaps that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects resulting from traumatic injury to the bone. AttraX Putty is intended to be used in conjunction with autograft bone as a bone graft extender and gently packed into bony voids or gaps in the posterolateral spine. AttraX Putty provides a bone void filler that resorbs and is replaced by the growth of new bone during the healing process.

DEVICE DESCRIPTION

AttraX Putty is a synthetic, osteoconductive and resorbable bone void filler device consisting of ceramic granules premixed with a polymeric binder that provides cohesion between the granules. The granules of AttraX Putty are composed of beta-tricalcium phosphate (β-TCP > 90%) and hydroxyapatite (HA <10 %). The granule size range is from 500 to 1000 µm. The premixed binder is alkylene oxide copolymer (AOC). AttraX Putty is provided in various configurations as cylinders, strips, and blocks.

EQUIVALENCE TO MARKETED DEVICE

AttraX Putty is substantially equivalent in indications and design principles to the following legally marketed predicate devices:

Progentix Orthobiology B.V., CuriOs™, cleared under K090641; and

ApaTech Limited, Actifuse™ Shape, cleared under K080736.

“AttraX Granules” is an alternate name for the predicate CuriOs™ device cleared under K090641. Therefore, the name AttraX Granules is used when referring to the predicate K090641 CuriOs™ device throughout this 510(k) submission.

The subject device and predicate devices K090641, and K080736 have the same intended use, the same product classification and product code (MQV), and have similar Indications for Use. Moreover, the subject device has the same AOC binder component as the predicate device K080736.

AttraX Putty is substantially equivalent to the predicate AttraX Granules (K090641) because AttraX Putty consists of equivalent ceramic granules with respect to design, structure, materials, testing, mechanism of action, and similar Indications for Use in the posterolateral spine. The 500 to 1000 µm granules size range used in K090641 is the exact same granules used in AttraX Putty to facilitate optimal handling. The only difference is that AttraX Putty has the granules premixed with a rapidly dissolving polymeric binder (AOC) that acts as a temporary binder for the granules. The polymeric binder used is Alkylene Oxide Copolymer (AOC), which also has been cleared in a similar bone void filler (Actifuse™ Shape, K080736).

Any differences in the technological characteristics between the subject and predicate devices do not raise new issues of safety or efficacy.

Non-clinical testing data submitted, referenced, or relied upon to demonstrate substantial equivalence included chemical composition, physical properties, biocompatibility, and performance characteristics. Biocompatibility testing was performed using methods described in ISO 10093-1, ISO 10093-3, ISO 10093-5, ISO 10093-6, ISO 10093-10, and ISO 10093-11.

Material characterization performed included the following:

- chemical composition and crystallinity was analyzed by x-ray diffraction (XRD), Fourier transform infrared spectroscopy (FTIR), and organic volatile impurity analysis (OVI),
- trace elemental analysis was performed by inductively coupled plasma/mass spectroscopy (ICP/MS),
- surface microstructure and mineralization were evaluated by scanning electron microscopy (SEM), and
- physical properties including porosity by mercury intrusion porosimetry, dissolution, and water content.

The analytical characterization demonstrated equivalent chemical composition, physical properties and performance characteristics for the subject AttraX Putty and the predicate AttraX Granules. In addition, the same AOC binder is used in combination with calcium phosphate granules in the predicate device Actifuse™ Shape, K080736.

The performance of the subject AttraX Putty was compared to that of the predicate AttraX Granules in a posterolateral spine fusion animal model. The results of the study demonstrated that the performance of the subject device was equivalent to that of the predicate.

The data included in this submission demonstrate substantial equivalence to the predicate devices listed above.

Overall, AttraX Putty has the following similarities to the predicate devices:

- has the same intended use,
- has the same product classification and product code (MQV),
- has similar Indications for Use,
- uses the same operating principle,
- incorporates the same basic design,
- incorporates the same or very similar materials, and is manufactured by same manufacturer using same processes as predicate, AttraX Granules (K090641).

CONCLUSION

The above testing demonstrates that AttraX Putty is as safe, as effective and performs or well as or better than the legally marketed predicate devices CuriOs™ (Progentix Orthobiology), and Actifuse™ Shape (Apatech).